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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* MARIANNE DRAGHEIM and IOANA FLOREA

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Appeal 2019-003984
Application 13/812,073[1]
Technology Center 1600

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Before FRANCISCO C. PRATS, ULRIKE W. JENKS, and CYNTHIA M. HARDMAN, *Administrative Patent Judges.*

HARDMAN, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims related to a method for the treatment of depression or anxiety in certain patients for more than twelve weeks using vortioxetine. The Examiner rejected the claims as obvious under 35 U.S.C. § 103(a) and for obviousness-type double patenting. We heard oral argument on July 16, 2020. We have jurisdiction under 35 U.S.C. § 6(b).

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real parties in interest as H. Lundbeck A/S and Takeda Pharmaceuticals America, Inc. Appeal Br. 2.

We affirm the obviousness rejection. However, because our affirmance includes reasoning somewhat different from the Examiner's, and because we rely on additional evidence not specifically relied upon by the Examiner, we designate our affirmance a New Ground of Rejection. We also affirm the obviousness-type double patenting rejections.

## CLAIMED SUBJECT MATTER

Claims 10, 34, 36–41, and 43–46 are on appeal. Non-Final Act.[2] 2. Independent claim 10, reproduced below, is illustrative of the claimed subject matter:

> 10. A method for the treatment of depression or anxiety, the method comprising the administration of a therapeutically effective amount of l-[2-(2,4-dimethyl-phenylsulfanyl)phenyl] piperazine[3] or a pharmaceutically acceptable salt thereof to a patient in need thereof for a treatment period of more than 12 weeks,
>
> wherein the patient has previously received medication or is still receiving medication for the treatment of depression or anxiety, the medication is ceased or has to be ceased due to weight gain, and the l-[2-(2,4-dimethyl-phenylsulfanyl)phenyl] piperazine or a pharmaceutically acceptable salt thereof is administered to the patient at a daily dose ranging from 2 mg to 40 mg.

Appeal Br. 29.

[2] Non-Final Action dated June 28, 2018.
[3] The claimed compound is also known as vortioxetine. *See* Appeal Br. 2. For brevity, we use the term vortioxetine herein.

REJECTIONS

The following rejections are before us for review:[4]

(1) claims 10, 34, 36–41, and 43–46 under 35 U.S.C. § 103 as being unpatentable over Artigas[5] and Moore[6] (Non-Final Act. 15);

(2) claims 10, 34, 36–41, and 43–46 on the ground of nonstatutory obviousness-type double patenting over claims 1, 6, 7, 9–11, 14 and 15 of U.S. Patent No. 9,278,096 (the "'096 Patent") in view of Artigas and Moore (*id.* at 4); and

(3) claims 10, 34, 36–41, and 43–46 on the ground of nonstatutory obviousness-type double patenting over claims 1, 5, and 7 of U.S. Patent No. 8,969,355 (the "'355 Patent") in view of Artigas and Moore (*id.* at 7–8).

OPINION

*Obviousness Over Artigas and Moore*

*Examiner's Findings*

The Examiner found that Artigas discloses a study wherein 5 mg or 10 mg vortioxetine HBr was administered to patients for six weeks, wherein the treatment effectively treated depression, with no relevant changes in weight. Non-Final Act. 15, 16. The Examiner further found that Moore

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[4] The Non-Final Action included a provisional rejection for nonstatutory obviousness-type double patenting over claims of copending Application No. 15/661,392 in view of Artigas and Moore. Non-Final Act. 11. Because this copending Application has been abandoned, we do not further discuss this rejection. *See* Application No. 15/661,392, Notice of Abandonment (dated June 25, 2020).

[5] Artigas et al., *A randomised, double-blind, placebo-controlled, active-referenced study of Lu AA21004 in patients with major depression*, 19 European Neuropsychopharmacology S426–S427 (2009) ("Artigas").

[6] Moore et al., WO 2009/062517 A1, published May 22, 2009 ("Moore").

teaches that vortioxetine has a unique pharmacological profile with an unexpectedly favorable safety profile, and is useful as a second line treatment for patients who cannot use other antidepressants, such as selective serotonin reuptake inhibitors ("SSRIs"), due to sleep- or sex-related adverse events. *Id.*

The Examiner found that one of ordinary skill in the art at the time of the invention would have been motivated to try providing vortioxetine to the claimed patient population to treat depression for more than 12 weeks because:

> 1) Artigas et al. teach that the HBr salt of the same compound administered [at] 5 mg or 10 mg doses daily is effective in treating depression wherein there is no relevant changes in weight after 6 weeks; and 2) Moore et al. teach [that vortioxetine] and salts thereof [are] useful for the treatment of depression and obesity for example in patients previously receiving treatment for depression and needed to stop due to the adverse reaction such as reduced sleep or a sexually related adverse event to an anti-depressant such as a noradrenaline/serotonin reuptake inhibitors or SSRI (see page 11, lines 10, 13 and 30).

*Id.* at 16–17.

*Analysis*

Considering the totality of evidence of record, we determine that the Examiner has presented a prima facie case of obviousness of the appealed claims over the combination of Artigas and Moore. Specifically, Artigas teaches a proof-of-concept study in patients with major depressive disorder. Artigas S426. Patients were treated with vortioxetine HBr for six weeks, and treatment was statistically significantly superior to placebo, with no clinically relevant changes in the clinical laboratory results, vital signs, or

weight. *Id.* Moore teaches that in clinical trials for depression, as compared to placebo, vortioxetine showed a statistically significant improvement of sleep pattern, and showed "that the sexual adverse effect of [vortioxetine] is similar to placebo [and] is thus much better than what would normally be expected from a[n] antidepressant, and in particular an SSRI." Moore 9:9–17, 10:7–8. Moore teaches that vortioxetine has a unique pharmacological profile and unexpectedly favorable safety profile, making it useful for the treatment of depression, including for long-term treatment and second line treatment for patients who cannot use other antidepressants (including SSRIs) due to sleep- or sex-related adverse events. *Id.* at 10:13–12:4.

We agree with the Examiner that in view of the teachings of Artigas and Moore, a skilled artisan would have been motivated to try vortioxetine as a second-line, long-term treatment of depression in the claimed patient population. Non-Final Act. 17–18. Artigas and Moore provide a reasonable expectation of success in meeting the limitations of the claimed invention, i.e., treating depression or anxiety for more than twelve weeks in the claimed patient population.[7] For example, in a proof-of-concept study, Artigas demonstrated the compound's success in treating depression for six weeks, and Moore teaches added benefits of the compound for long-term treatment and second line treatment for patients who cannot use other antidepressants (albeit due to unrelated side effects). We further discuss our reasoning and address Appellant's arguments below.

[7] As will be discussed further below, because the claims do not require that the claimed treatment be associated with lack of weight gain, there is no requirement for a reasonable expectation of success with respect to this attribute.

*Claims 10 and 34*

Appellant argues that "the Office failed to show how all claim limitations are taught or suggested by Artigas and Moore," because these references do not teach or suggest treatment for more than six weeks. Appeal Br. 12–13, 14. We are not persuaded by this argument. Persons of ordinary skill in the art understood that long-term treatment for depression is often required. For example, Moore discusses long-term and chronic treatments for depression, and the utility of vortioxetine for such extended treatments. *See, e.g.*, Moore 10:13–18 ("The absence of these adverse effects [sleep and sexual activity disruptions] in treatments comprising the administration of compound I makes compound I particular[ly] useful in therapeutic interventions over an extended period of time, such as e.g. depression relapse prevention."). Additionally, Dr. Dragheim acknowledged that "[m]ost patients require long-term treatment for depression." Dragheim Decl.[8] ¶ 5 (quoting Baldwin[9] 31).

Appellant also argues that Artigas does not teach or suggest whether "longer-term treatment . . . would be expected to show no clinically relevant weight change." Appeal Br. 13. We are not persuaded by this argument, because the appealed claims do not recite any limitation requiring a lack of clinically relevant weight change. Thus, there is no need for the asserted prior art combination to teach such a limitation.

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[8] Declaration of Marianne Dragheim under 37 C.F.R. § 1.132, dated September 4, 2015 ("Dragheim Decl.").
[9] Baldwin, D.S., *The importance of long-term tolerability in achieving recovery*, 10 (Supp. 1) Int. J. Psychiatry in Clin. Prac. 31–37 (2006) (attached as Ex. 3 to Dragheim Decl.) ("Baldwin").

Appellant further argues that neither Artigas nor Moore teaches or suggests treating the claimed subpopulation, i.e., patients who stopped or need to stop taking medication for the treatment of depression or anxiety due to weight gain. *Id.* at 12, 15. We are not persuaded by this argument. First, we agree with the Examiner that Moore indicates that "it is known in the art to switch medications when adverse effects occur in patients to another antidepressant, particularly the claimed compound." Ans. 21. Second, as acknowledged in the Specification and as is clear from the record, the claimed patient population was known in the prior art. *See* Spec. 6:22–23 (indicating that "many patients who experience treatment emergent weight gain are reluctant to take the drug as prescribed"); Zajecka[10] 61 ("[M]any patients prematurely discontinue their medication as a result of increased appetite or weight gain."); Papakostas II[11] ¶¶ 16, 19; *see also Prometheus Labs., Inc. v. Roxane Labs., Inc.*, 805 F.3d 1092, 1099–01 (Fed. Cir. 2015) (finding that it would have been obvious to treat the claimed subpopulation of irritable bowel syndrome patients based on common practices in the field).

Appellant additionally argues that "there is no reasonable expectation that treatment of depression with vortioxetine would be effective for more than 12 weeks without significant weight gain" in the claimed subpopulation, because one cannot predict which adverse effects a patient will experience or the net side effect profile of a compound such as

[10] Zajecka, J. M., *Clinical Issues in Long-Term Treatment with Antidepressants*, 61 (Supp. 2) J. Clin. Psychiatry 20–25 (2000) (attached as Ex. 2 to Dragheim Decl.) ("Zajecka").
[11] Supplemental Declaration of George Papakostas, M.D. Under 37 C.F.R. § 1.132, dated August 29, 2017 ("Papakostas II").

vortioxetine, which has multiple mechanisms of action. Appeal Br. 16–17; *see also id.* at 17–18 (citing, e.g., Papakostas II ¶¶ 17, 24, 25; Dragheim Decl. ¶¶ 5–8, 12). Appellant additionally argues that Moore's teachings regarding vortioxetine's beneficial effects on sleep- and sex-related adverse events do not translate to a reasonable expectation "that vortioxetine would be useful to treat depression patients without long-term weight gain" because "side-effects are not expected to be directionally correlated with one another." *Id.* at 19 (citing, e.g., Papakostas II ¶ 23; Papakostas I[12] ¶ 16). Appellant additionally argues that the claimed invention is not obvious to try because the "impact on reducing long-term weight gain is not predictable." Appeal Br. 21; *see also id.* at 21–22 (citing, e.g., Papakostas II ¶¶ 17, 23–30; Dragheim Decl. ¶¶ 5–8, 12, 13).

We are not persuaded by these arguments, because they are not tied to the claimed method. "The reasonable expectation of success requirement refers to the likelihood of success in combining references *to meet the limitations of the claimed invention*." *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016) (emphasis added). Here, the appealed claims do not recite any requirements relating to lack of weight gain from long-term vortioxetine treatment, and thus there is no requirement to show a reasonable expectation of success related to lack of weight gain. *See id.* (finding that, where the claim did not require quantitative removal of protecting group, it was "of no moment" that prior art did not provide a reasonable expectation of success of quantitative removal); *see also BTG Int'l Ltd. v. Amneal Pharms. LLC*, 923 F.3d 1063,

[12] Declaration of George Papakostas, M.D. Under 37 C.F.R. § 1.132, dated October 23, 2016 ("Papakostas I").

1075, 1076 (Fed. Cir. 2019) (rejecting appellants' arguments about a lack of reasonable expectation of success of anti-cancer effect and survival advantage where the subject claims did not require such attributes).

Appellant also argues that the claimed invention is not obvious to try because given the large number of antidepressants, many of which result in weight gain, there is no "'finite number of identified' solutions from which to choose in order to treat depression without long-term weight gain." Appeal Br. 21 (citing Papakostas I ¶ 21; Papakostas II ¶¶ 13, 17). We are not persuaded by this argument. First, we again note that the claim does not require a lack of long-term weight gain. Second, even though there may have been a large number of available antidepressants (*see, e.g.*, Papakostas I ¶ 21 (listing antidepressants)), the prior art gave direction on which were more frequently associated with weight gain. *See, e.g.*, Cassano[13] 17 (discussing weight gain observed in long-term clinical studies for various antidepressants); Serretti[14] 1260 (presenting "quantitative review of the literature regarding the effect on body weight potentially exerted by the most common antidepressant drugs").

Accordingly, we agree with the Examiner that "since Artigas demonstrated the compound[']s success in treating short-term depression without weight gain" and, as will be further discussed below in connection with unexpected results, the majority of patients do not experience weight

[13] Cassano et al., *Tolerability Issues During Long-Term Treatment with Antidepressants*, 16 Annals of Clinical Psychiatry 15–25, 17 (2004) ("Cassano," attached as Ex. 1 to Dragheim Decl.).
[14] Serretti et al., *Antidepressants and Body Weight: A Comprehensive Review and Meta-Analysis*, 71(10) J. Clin. Psychiatry 1259–1272 (2010) ("Serretti," attached as Ex. 5 to Dragheim Decl.).

gain with long-term treatment with many serotonin reuptake inhibitors, a skilled artisan would have been motivated to try vortioxetine for the treatment of depression for more than twelve weeks. Ans. 21; *see also id.* at 20 ("[T]he majority of patients (77–75%) in long-term care for depression with SSRIs do not have weight gain."). We agree with the Examiner that given "the fact that the majority of patients taking long term treatment for depression with serotonin reuptake inhibitors do not experience weight gain, and the special characteristics of the instantly claimed compound to be used as a second line treatment for patients with depression who cannot use antidepressants such as SSRls, one would have [had] a reasonable expectation of success that the instantly claimed compound would provide long-term treatment for depression to the patient population claimed." *Id.* at 22.

Appellant argues several objective indicia of nonobviousness, including unexpected results. Specifically, Appellant argues that although clinicians would have expected vortioxetine to cause long-term weight gain, the converse is true. Appeal Br. 23; *see also* Papakostas II ¶ 25; Dragheim Decl. ¶¶ 5, 9, 12; Spec. 15:1–3, 16:5–7; *see also* Appeal Br. 19–20 (discussing unexpected results and additionally citing Dragheim Decl. ¶¶ 3, 9; Papakostas I at ¶¶ 13, 22; Papakostas II ¶¶ 17, 23, 27, 31). Appellant additionally argues that "regulatory agencies in the U.S. and Europe approved vortioxetine to treat depression and recognized that vortioxetine has a low level of weight-related adverse events." Appeal Br. 23 (citing Dragheim Decl. ¶¶ 9–10).

We are not persuaded that Appellant has demonstrated unexpected results. Appellant contends that vortioxetine's "low level of weight-related

adverse events" is unexpected because clinicians would have expected that agents that inhibit serotonin reuptake (like vortioxetine) would cause long-term weight gain. *Id.* We acknowledge the opinions offered by Drs. Papakostas and Dragheim regarding this purported expectation (e.g., Papakostas II ¶ 25; Dragheim Decl. ¶ 5), but find that the totality of evidence of record does not corroborate such an expectation. *See, e.g.*, *In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1368 (Fed. Cir. 2004) ("[T]he Board is entitled to weigh the declarations and conclude that the lack of factual corroboration warrants discounting the opinions expressed in the declarations.").

Rather, we agree with the Examiner that the evidence of record indicates that the majority of patients taking long term treatment for depression with serotonin reuptake inhibitors do not experience weight gain. Ans. 20–21. For example, Cassano indicates that within the SSRI class, weight gain associated with long-term therapy affects a minority of patients, and the rate of weight gain among patients varies from agent to agent. Specifically, Cassano reports that after six months of therapy, the rate of significant weight gain was approximately 25% for paroxetine, 8% for fluoxetine, and 4% for sertraline. Cassano 17. Cassano also recognizes that while weight gain is a "relatively common side effect[] of chronic treatment, . . . in some studies the occurrence of these long-term side effects was similar in placebo-treated patients." *Id.* (indicating that "significant (i.e., ≥7% of body weight) weight gain occurred in 4.8% of fluoxetine-treated patients vs. 6.3% of placebo-treated patients in a 6-month study") (citation omitted). Additionally, Serretti reports that "no significant effect [on body weight] could be observed for citalopram during maintenance treatment."

Serretti 1267; *see also id.* at 1263 (indicating that "maintenance" refers to treatment periods greater than four months).

Thus, while the record reflects that weight gain is a possibility for some patients on long-term SSRI therapy, we agree with the Examiner that the record indicates that "the *majority* of patients administered serotonin reuptake inhibitors for the treatment of long-term depression *do not have weight gain*." Ans. 26. Further, Cassano teaches that "intolerance to one SSRI is not predictive of intolerance to other SSRIs." Cassano 17. Accordingly, on this record, Appellant has not persuasively established an expectation that vortioxetine would cause long-term weight gain based on its serotonin reuptake inhibitory action, such that vortioxetine's lack of weight-related adverse events is unexpected. *See Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1371 (Fed. Cir. 2007) ("[B]y definition, any superior property must be *unexpected* to be considered as evidence of non-obviousness.").

Moreover, Appellant must prove a nexus between any proffered unexpected results and the merits of the claimed invention. *See In re GPAC Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995). Here, the claims are directed to treatment with vortioxetine in a specific subpopulation, but on this record, we have not been directed to information regarding whether any of the participants in the vortioxetine studies that established the lack of weight-related adverse events fell within the claimed subpopulation and experienced the lack of weight-related adverse events. *See, e.g.*, Spec. 13:12–19 (discussing study design but providing no details on whether subjects were in the claimed subpopulation), 15:6–13 (same). Similarly, we have not been directed to information regarding whether the regulatory approval or

recognition by regulatory agencies of a low level of weight-related adverse events was tied to the claimed subpopulation.

Appellant additionally argues that "clinicians recognized a long-felt unmet need for anti-depressant therapies with reduced long-term weight gain," and that "SSRIs [have] failed to provide effective anti-depressant therapy without long-term weight gain." Appeal Br. 24 (citing Papakostas II ¶¶ 16–18; Dragheim Decl. ¶ 7). We are not persuaded by these arguments, because as discussed above, the record indicates that not all SSRIs are associated with significant long-term weight gain, and not all patients experience long-term weight gain. Additionally, Appellant's argument regarding a long-felt, unmet need for anti-depressant therapies with reduced long-term weight gain lacks a nexus with the appealed claims. As discussed above, the appealed claims only require an effective treatment for depression or anxiety in treatments greater than twelve weeks; they do not recite any limitations related to lack of weight gain. Because other effective antidepressants were available for long-term treatment, we are not persuaded that Appellant has established a long-felt, unmet need that was solved by the claimed invention. *See BTG Int'l Ltd.*, 923 F.3d at 1076 ("The Asserted Claims only require an effective treatment for prostate cancer. . . . [B]ecause other treatments for prostate cancer were available, the evidence presented here does not establish that there was a specific unsolved, long-felt need for the treatment.").

*Claims 40 and 41*

Independent claim 40 and dependent claim 41 recite that the patient has ceased other anti-depressant or anti-anxiety medications due to weight gain, and the ceased medication is a serotonin re-uptake inhibitor. *See*

Appeal Br. 30 (Claims Appendix). For these claims, Appellant additionally argues that because "long-term weight gain remains a problem with SSRIs," clinicians would expect other SSRIs to also cause long-term weight gain, but vortioxetine is "weight neutral." *Id.* at 25–26 (citing, e.g., Papakostas II ¶ 25; Dragheim Decl. ¶ 12). We are not persuaded by this argument, because as discussed above, on this record Appellant has not persuasively established that long-term weight gain is a problem with all SSRIs for all patients.

*Claims 36–39*

Claims 36–39 indirectly depend from claim 40, and recite specific daily doses of vortioxetine HBr. *See* Appeal Br. 29–30 (Claims Appendix). For these claims, Appellant additionally argues that "it would require extensive experimentation to arrive at the claimed doses" because "it would take several months before a clinician can decide whether a given dose of vortioxetine would cause long-term weight gain." *Id.* at 26 (citing, e.g., Papakostas I ¶ 21; Papakostas II ¶ 30). We are not persuaded by this argument, because as discussed above, the claims do not require a lack of long-term weight gain.

*Claims 43–46*

Claims 43–46 indirectly depend from claim 40, and additionally recite specific daily doses of vortioxetine HBr in patients for a treatment period of more than 12 weeks, wherein the patients have ceased other anti-depressant or anti-anxiety medications due to weight gain, and the ceased medication is a serotonin re-uptake inhibitor. *See* Appeal Br. 30–31 (Claims Appendix). With respect to these claims, Appellant essentially reiterates the arguments it

made for claims 36–41. *See id.* at 27–28. We apply our analyses for claims 36–41 to claims 43–46.

*Summary – Obviousness Over Artigas and Moore*

In sum, we agree with the Examiner that the combination of Artigas and Moore would have rendered claims 10, 34, 36–41, and 43–46 obvious. However, because our reasoning differs somewhat from that of the Examiner, we designate this rejection a New Ground under 37 C.F.R. § 41.50(b) to provide Appellant with a full and fair opportunity to respond to the rejection.

*Obviousness-Type Double Patenting*

On appeal, Appellant does not address the Examiner's nonstatutory obviousness-type double patenting rejections. *See generally* Appeal Br. Arguments not presented in a brief are waived. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2015) ("Except as provided for in §§ 41.41, 41.47 and 41.52, any arguments or authorities not included in the appeal brief will be refused consideration by the Board for purposes of the present appeal."). Additionally, Appellant has not filed a terminal disclaimer that would moot these rejections. Accordingly, we summarily affirm the uncontested nonstatutory obviousness-type double patenting rejections.

CONCLUSION

We affirm the rejection of claims 10, 34, 36–41, and 43–46 under 35 U.S.C. § 103 as being unpatentable over Artigas and Moore, but designate our affirmance a New Ground of Rejection because our conclusion of obviousness includes reasoning and evidence not specifically relied upon by the Examiner.

We affirm the rejection of claims 10, 34, 36–41, and 43–46 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6, 7, 9–11, 14, and 15 of the '096 Patent in view of Artigas and Moore.

We affirm the rejection of claims 10, 34, 36–41, and 43–46 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, and 7 of the '355 Patent in view of Artigas and Moore.

DECISION SUMMARY

| **Claims Rejected** | **35 U.S.C. §** | **Reference(s)/ Basis** | **Affirmed** | **Reversed** | **New Ground** |
|---|---|---|---|---|---|
| 10, 34, 36–41, 43–46 | 103 | Artigas, Moore | 10, 34, 36–41, 43–46 | | 10, 34, 36–41, 43–46 |
| 10, 34, 36–41, 43–46 | | Obviousness-type double patenting over claims 1, 6, 7, 9–11, 14, 15 of the '096 Patent, Artigas, Moore | 10, 34, 36–41, 43–46 | | |
| 10, 34, 36–41, 43–46 | | Obviousness-type double patenting over claims 1, 5, 7 of the '355 Patent, Artigas, Moore | 10, 34, 36–41, 43–46 | | |
| **Overall Outcome:** | | | 10, 34, 36–41, 43–46 | | 10, 34, 36–41, 43–46 |

TIME PERIOD FOR RESPONSE

This Decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b). 37 C.F.R. § 41.50(b) provides that "[a] new ground of

rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new grounds of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution*. Submit an appropriate amendment of the claims so rejected or new Evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the prosecution will be remanded to the examiner. . . .
>
> (2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same Record. . . .

Should Appellant elect to prosecute further before the Examiner pursuant to 37 C.F.R. § 41.50(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the Examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

Further guidance on responding to a new ground of rejection can be found in the Manual of Patent Examining Procedure § 1214.01.

AFFIRMED
37 C.F.R. § 41.50(b)